

Application No. 08/499,423

Claim 33 (four times amended)

*33*

33. An article comprising a porous polytetrafluoroethylene tube having a first circumference at a first internal pressure of atmospheric pressure, a second circumference at a second internal pressure of greater than atmospheric pressure, said second circumference being greater than the first circumference, wherein upon applying an internal pressure greater than the second internal pressure, the porous polytetrafluoroethylene tube itself limits further growth beyond the second circumference.

Claim 46 (once amended):

*46*

46. A tube according to claim 42 wherein the tube comprises a vascular graft.

REMARKS**I. PRELIMINARY REMARKS**

Claims 1, 3-33, 35, 42-69, 71-77, 79-88 and 91-97 are pending in the application. Claims 46-57 are objected to as being of improper dependent form. All claims are rejected as unpatentable over prior art.

The necessary petition for the appropriate extension of time (and required fee) is submitted herewith.

**II. APPLICANTS' INVENTION**

The present invention relates to a porous polytetrafluoroethylene tube that circumferentially distends from an initial circumference upon the application of a circumferentially distending force such as applied by an internal pressure, and which preferably exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene tube preferably has a second circumference larger than the initial circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene tube itself provides the circumferential distensibility up to the limiting second circumference, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can

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smoothly conform. The tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilatation of the blood vessel into which it is fitted.

**III. OBJECTION TO CLAIMS 46-57 UNDER 37CFR1.75(c) AS BEING OF IMPROPER DEPENDENT FORM.**

The Examiner has pointed out that the "porous polytetrafluoroethylene" limitation of claim 46 is redundant to the same limitation in claim 42 from which claim 46 depends. Claim 45 is now canceled and claim 46 amended to replace the "porous polytetrafluoroethylene" limitation with the limitations of now-canceled claim 45. Amending in this manner allows for the dependencies of claims 47-57 to remain correct without amendment.

**III. REJECTION OF CLAIMS 1, 3-17, 19-31, 33, 35, 42-69, 71-77, 79-88 AND 91-97 UNDER 35 USC 102(e) AS ANTICIPATED BY SHANNON et al., US 5,641,373.**

Shannon et al. describe an ePTFE tube provided with a helical wrapping of a reinforcing material.

The Examiner rejects these claims on the grounds that the limitation of claim 1, of applying internal pressure up to a second circumference such that the tube "limits further growth in the second circumference to remain substantially unchanged" or in claim 33, "limits further growth to substantially the second circumference" fails to distinguish the expansion beyond the second circumference as being different from the first to second circumferential expansion. He adds that the claim language reads on a further expansion up to the second circumference.

Claims 1 and 33 are amended herein to make it further clear that the increasing tube circumference is a function of increasing internal pressure, but the increase in circumference substantially ceases with further increasing pressure once the second circumference is achieved. Claims 1 and 33 (as amended) are both clear in this regard. As to the use of the word "substantially" in the respective phrases "...so as to remain substantially unchanged from the second circumference with further increasing pressure" (claim 1) and "...tube itself limits further growth to substantially the second circumference" (claim 2), it must be remembered that these are porous, very flexible and often quite thin polymeric tubes. The physical characteristics of the tubing preclude precision in the measurement of diameter or circumference under pressure. Further, consistent with the specification description, a slight increase in circumference may be expected as the pressure increases beyond the pressure necessary to achieve the second, limiting

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circumference, but not at all like the rate of circumferential change experienced by the tube with the pressure increase that resulted in the change from original ("first") circumference to the second circumference.

The Examiner further states "that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited."

The claimed physical property with respect to independent claims 1 and 33 (i.e., limiting the tube circumference to substantially a second circumference, appreciably larger than the initial, first circumference, upon exposure to increasing internal pressure) is not "recoil." Recoil (described frequently in the specification, see particularly page 7, line 28 to page 8, line 27) is that property whereby a porous polytetrafluoroethylene tube will, due to the "memory" of the polymeric tubing, try to return to the original, first circumference once the internal pressure responsible for achieving a larger, second circumference has been removed.

Claims 10-13 and 42-44 relate to tubes having minimal recoil.

It must be apparent to the man of ordinary skill in the art of PTFE tubes that that these properties are inherent in the prior art. Lacking this, these claims, as amended, are not anticipated by the cited references.

**IV. REJECTION OF CLAIMS 1, 3-5, 24-26, 33, 35, 86-88 AND 91 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY DELLA CORNA et al., US 4,955,899.**

The Examiner rejected these claims over Della Coma et al. for substantially the same reasons given in the above-described rejection based on Shannon et al. The ensuing arguments relate to the claims as amended herein. The amendments pertain to the Examiner's arguments regarding the Della Coma et al. reference in the same fashion as they relate to Shannon et al., as described above.

Della Coma et al. describe an ePTFE tube that is made to be longitudinally compliant by compressing a precursor, standard ePTFE tube longitudinally and coating it in the compressed state with an elastomer. The compliant coating causes the to retain the compressed length and provides the tube with a measure of longitudinal extensibility. Nothing is done, however, to affect the diametrical or circumferential properties of the tube as it is exposed to increased internal pressure.

The ePTFE-based vascular grafts taught by Della Coma et al. have the same fundamental behavior with regard to pressure vs. diameter as do the prior art ePTFE tubes described in the background of the present application. Please see page 2, line 15 to page 3, line 2, particularly

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the paragraph beginning at page 2, line 29 describing the prior use of GORE-TEX® vascular Grafts and IMPRA® Grafts (Della Corna et al. being assigned to Impra). Briefly, the GORE-TEX® Vascular Grafts are longitudinally extruded and expanded (by longitudinal stretching) ePTFE tubes that are provided with a helical wrap of ePTFE film that results in a graft with resistance to dilatation; the graft will maintain substantially the same diameter until the pressure reaches a level that will cause the onset of rupture. When this pressure is achieved, the graft will very quickly rupture. The IMPRA® Graft is made in the same fashion except that it is not provided with the helical film wrap. The diameter of such a tube can be expected to increase continually with steadily increasing pressure until the onset of rupture, at which point further increasing pressure will result in abrupt rupture in a manner similar to the GORE-TEX® Vascular Graft.

The man of ordinary skill in the art of ePTFE tubes is well aware of this typical behavior whereby the tube diameter and circumference increase with increasing pressure until ultimately rupture occurs. It is well understood that there is no limiting "second circumference" at which the tube circumference stabilizes (until pressures approaching the burst pressure are achieved). There is nothing whatsoever in the reference to indicate that the tube of Della Corna et al. is any different in this regard.

The present graft differs from all of these prior art ePTFE tubes (including Della Corna et al.) because it is manufactured in an entirely different and new manner; please see the flow chart of Figure 4. As a result, the graft of the present invention is able to be provided at a small diameter for catheter insertion into the vasculature (e.g., 1 mm, per Example 6, page 20), and then be increased in diameter (up to a pre-determined diameter, e.g., 8-9mm, again per Example 6) by a distending force such as supplied by a catheter balloon or even blood pressure, depending on the details of manufacture. Once this pre-determined diameter ("second circumference") is achieved, the inventive graft will resist further diametrical increase until the pressure approaches the burst pressure of the tube. This behavior is entirely different from the behavior of the tubes of Della Corna et al. They give absolutely no suggestion as to how an ePTFE tube might be made to allow a relatively low-pressure increase in diameter up to a limit (the "second circumference"). They simply do not provide the stable "second circumference" in any fashion.

The typical behavior of ePTFE tubes exposed to increasing internal pressure, i.e., without a limiting second circumference, is, as stated previously, well understood to those of skill in the ePTFE tube art. There is nothing in Della Corna et al. to lead the man of ordinary skill to believe otherwise, as there must be for the tube behavior in question to be considered inherent in the reference. It is well established that if a claim limitation is inherently disclosed in a reference, it

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must be necessarily present and a person of ordinary skill would recognize its presence. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); Continental Can, 948 F.2d at 1268, 20 USPQ2d at 1749. Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1269, 20 USPQ 2d at 1749 (quoting In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)). A prior art patent may not be assumed to contain inherently a claim limitation of the patent in suit simply because the reference discloses the same structure (Crown Operations Int'l Ltd. v. Solutia Inc., CAFC, No. 01-1144, 5/13/02).

Accordingly, Della Corna et al. do not anticipate these claims.

**V. REJECTION OF CLAIM 18 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER SHANNON et al., US 5,641,373 IN VIEW OF HUGHES et al., US 4,728,328.**

Shannon et al. are described above. Hughes et al. teach the manufacture of a vascular prosthesis having cuffed ends, including an embodiment incorporating three ends (Figure 12) which is not taught by Shannon et al.

Claim 18 relates to a branched vascular graft having three ends. It depends, sequentially, from claims 14, 6, 5 and 1. As the claims from which it depends are argued above to be patentable over the Shannon et al. reference, claim 18 is accordingly also patentable.

**VI. REJECTION OF CLAIM 32 UNDER 35 USC 103(a) AS UNPATENTABLE OVER DELLA CORNA et al., US 4,955,899 IN VIEW OF HUGHES, US 4,728,328.**

Della Corna et al. are described above. Hughes et al. (as described above) teach the manufacture of a vascular prosthesis having cuffed ends, including an embodiment incorporating three ends (Figure 12) which is not taught by Della Corna et al.

Claim 32 also relates to a branched vascular graft having three ends. It depends from claim 1. As claim 1 is argued above to be patentable over the Della Corna et al. reference, claim 32 is accordingly also patentable.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

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The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Claim 1 (four times amended):

1. An article comprising a porous polytetrafluoroethylene tube having a circumference wherein the circumference of said porous polytetrafluoroethylene tube increases in response to the application of internal pressure up to a second circumference, thereafter the tube itself limits further growth in the circumference so as to remain substantially unchanged from the second circumference with further increasing internal pressure.

Claim 33 (four times amended)

33. An article comprising a porous polytetrafluoroethylene tube having a first circumference at a first internal pressure of atmospheric pressure, a second circumference at a second internal pressure of greater than atmospheric pressure, said second circumference being greater than the first circumference, wherein upon applying an internal pressure greater than the second internal pressure, the porous polytetrafluoroethylene tube itself limits further growth beyond[to] the second circumference.

Claim 46 (once amended):

46. A tube according to claim 42[45] wherein the tube comprises a vascular graft[ is comprised of porous polytetrafluoroethylene].